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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,559	03/08/2004	Clark R. Baker JR.	TYHC:0150/FLE (P0424R)	1083

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EXAMINER

BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,559

Applicant(s)

BAKER, CLARK R.

Examiner

Etsub D. Berhanu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/08/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: element 144, Figure 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 6, 7, 9, 10, 13, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Conlon et al.'126.

Conlon et al.'126 discloses a method of ensemble averaging signals in a pulse oximeter comprising: receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to two different wavelengths of light (col. 3, lines 31-38); obtaining an assessment of the signal quality of the electromagnetic signals (col. 9, lines 41-47); selecting weights for an ensemble averager using the assessment of signal quality (col. 10, lines 22-29); and ensemble averaging the electromagnetic signals using the ensemble averager (col. 9, lines 61-68 and col. 10, lines 1-2).

Conlon et al.'126 further discloses methods for obtaining an assessment of the signal quality comprising: detection of motion artifact (col. 5, lines 13-16); obtaining a ratio of a current pulse amplitude to the previous pulse amplitude (col. 8, lines 23-35); obtaining a measure of the degree of the overall signal quality metric for a single pulse (col. 6, lines 28-41).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 2, 3, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlon et al.'126, as applied to claims 1 and 10, further in view of Mortz'277 (US Patent No. 5,934,277).

Conlon et al.'126 discloses all the elements of the current invention, as discussed in paragraph 4, except a method comprising obtaining an assessment of the signal quality by obtaining a measure of the degree of arrhythmia of the signals, and obtaining a measure of the degree of similarity or correlation between the first and second electromagnetic radiation signals; and a device for obtaining said assessments.

Mortz'277 teaches that the presence of good data is indicated by a linear relationship between mathematically processed red signal values and mathematically processed infrared signal values (col. 3, lines 54-57), and that a goodness-of-fit correlation coefficient can be used to indicate a probe-off condition or patient motion (col. 4, lines 38-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and device of Conlon et al.'126 to include obtaining a measure of the degree of arrhythmia of the signals and the degree of correlation between the first and second signal, and a means for obtaining said measurements, as taught by Mortz'277, since obtaining these measurements would indicate good data and a probe-off condition or patient motion.

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8. Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlon et al.'126 as applied to claims 1, 4, and 10.

Conlon et al.'126 teaches a method of comparing a current pulse amplitude to a long-term average amplitude threshold of signals (col. 8, lines 19-40 and Figure 11, blocks 268 and 274) in order to detect an acceptable R-wave. While Conlon does not particularly teach determination of a ratio, it would have been within the scope of the art to obtain a ratio of current pulse amplitude to a long-term average amplitude to assess signal quality, since the greater than/less than comparison of the current pulse amplitude to the long-term average amplitude is mathematically equivalent when expressed as a ratio of greater than 1 or less than 1.

9. Claims 1, 8, 10 and 17 are rejected under 35 U.S.C. 103(a) as being anticipated by Corenman et al.'167 (US Patent No. 4,911,167).

Corenman et al.'167 discloses a method of ensemble averaging signals in a pulse oximeter comprising: passing red and infrared light through a patient's blood perfused tissue and detecting the transmitted light, providing optical signals (col. 5, lines 67-68 and col. 6, lines 1-4); obtaining an assessment of the signal quality of the signals (col. 18, lines 66-68 and col. 19, lines 1-15); selecting weights for an ensemble averager and ensemble averaging the signals (col. 6, lines 32-40 and col. 9, lines 14-33); wherein obtaining an assessment of the signal quality comprises comparing a current pulse period to that of an average pulse period of the signals (col. 8, lines 3-32).

Corenman et al.'167 teaches that optimal performance occurs when the most recent information is given a weight of 1/6 while the historical weight-averaged composite information is given a weight of 5/6 (col. 8, lines 33-42). It would have been within the scope of the art to obtain a ratio of current pulse period to that of an average pulse period of signals to assure a 1/6 to 5/6 ratio to achieve optimal performance of signal processing.

Conclusion


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Heckel 6,839,582 teaches a pulse oximeter method and system with improved motion correction, Baker et al. 6,721,584 teaches a method and apparatus for estimating physiological parameters using filtering and ensemble averaging.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571.272.4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB



ERIC F. WINAKUR
EXAMINER